

### **REMARKS**

Please reconsider the application in view of the above amendments and the following remarks.

#### **Interview and Claim Amendments**

The Applicant thanks the Examiner for the interview of May 6, 2003 ("the Interview"). During this interview a preliminary agreement was reached that the amendment of the independent claims to recite that the orthopedic apparatus does not extend under a first metatarsal would suffice to overcome the § 102 and § 103 rejections over the Rothbart reference. Accordingly, the claims have been amended in accordance with this preliminary agreement in order to place the application in condition for allowance.

No new matter has been added by way of these amendments.

#### **Summary of the Invention**

Embodiments of the instant invention relate to providing a wedge underneath a toe in order to provide for increased stability during ambulation. An advantage of the invention is the ease of application of the device, in that it may be disposed beneath the hallux as part of a sole in footwear, adhered to the sole after manufacture, or, in the absence of footwear, may be adhered to the hallux. Providing such a wedge beneath the hallux alleviates the pain of certain medical conditions while mitigating the effects of a number of degenerative conditions of the foot.

#### **Rejections under 35 U.S.C. § 102**

The Examiner rejected claims 1-4, 6, and 10-14 under 35 U.S.C. § 102(e) as being anticipated by Rothbart, U.S. Patent No. 6,092,314 ("the '314 patent"). To the extent this rejection applies to the amended claims, it is respectfully traversed.

The '314 patent discloses a device extending from the hallux through the posterior end of the first metatarsal (Col. 6, L. 30-37 and referencing Fig. 6). Furthermore, the device of the '314 patent is clearly intended to be a "foot support system" (Col. 6, L. 14) having an elongate bed "on which a portion of the foot rests" (Col. 6, L. 16). The '314 patent claims an "elongate bed" extending along "the first toe and first metatarsal" (Col. 10, L. 54 and Col. 12, L.

18). This language clearly indicates that the '314 patent differentiates the toe and first metatarsal and targets a portion of the foot, as apposed to the toe alone. Furthermore, this language differentiates the apparatus of the '314 patent from the instant device, which is intended to provide direct support only to the toe and immediate area. Claims 1 and 10, as amended, are limited to the toe region exclusive of the first metatarsal. Specifically, claims 1 and 10 include the "not extending under a first metatarsal" limitation. Rothbart '314 does not include this limitation. Therefore, it cannot anticipate the present invention. Claims 2-4, 6, and 10-14 depend from claims 1 and 10, and therefore, are not anticipated by Rothbart '314 for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 1, 5, and 10-11 were rejected as being anticipated by U.S. Patent No. 4,333,472, issued to Tager ("the '472 patent"). To the extent that this rejection applies to the amended claims, it is respectfully traversed.

The '472 patent discloses a series of differentially-sized geometrically-shaped prosthetic devices to be disposed in footwear. These devices may be situated underneath a region extending from the calcaneum bone of the rear foot (See Fig. 7 and Col. 4, ll. 9-14) to the first metatarsal/first phalanx region (See Fig. 9 and Col. 4, ll. 35-37). In any embodiment of the '472 patent that is positioned under a phalanx, the device will also extend underneath a first metatarsal.

In contrast, independent claims 1 and 10 of the instant application, as amended, include the limitation that the orthopedic appliance does not extend under a first metatarsal. Accordingly, these claims are patentable distinct over the '472 patent. Claims 5 and 11, which depend from claims 1 and 10, respectively, are similarly patentable. Accordingly, withdrawal of this rejection is respectfully requested.

### **Rejections under 35 U.S.C. § 103**

Claims 4 and 5 were rejected as being obvious over the '314 patent. To the extent that this rejection applies to the amended claims, it is respectfully traversed, on the grounds that the '314 patent teaches away from the instant device.

The instant device provides direct support of the immediate toe area. Independent claim 1 of the instant application, as amended, includes the limitation that the orthopedic appliance does not extend under a first metatarsal. The '314 patent is targeted at an entire area of the foot "from the hallux 48 to the navicular 28" (Col. 6, L. 19-20). Furthermore, the '314 patent teaches that the back edge of the device may lie in a position posterior to the first metatarsal and more specifically, the back edge should extend into an area between the posterior end of the first metatarsal and the anterior end of the plantar surface of the calcaneus (Col. 6, L. 30-37). Thus, the '314 patent clearly teaches away from the instant device, which lies substantially under the toe. Claims 4 and 5 depend from claim 1 and include the limitation, "not extending under a first metatarsal." Therefore, the '314 patent cannot render claims 4 and 5 obvious. Accordingly, withdrawal of this rejection is respectfully requested.

With regards to the rejection of claims 7-9 and 15-23 as being obvious over the '314 patent in view of either Brock '927 or Jacoby '046, Applicant respectfully traverses this rejection to the extent that it may apply to the amended claims, on the grounds that the '314 patent teaches away from the instant device.

The focus of the instant device is direct support of the immediate toe area. Independent claims 1, 10, and 18 of the instant application, as amended, include the limitation that the orthopedic appliance does not extend under a first metatarsal. The '314 patent is targeted at an entire area of the foot "from the hallux 48 to the navicular 28" (Col. 6, L. 19-20). Furthermore, the '314 patent teaches that the back edge of the device may lie in a position posterior to the first metatarsal and more specifically, the back edge should extend into an area between the posterior end of the first metatarsal and the anterior end of the plantar surface of the calcaneus (Col. 6, L. 30-37). Thus, the '314 patent teaches away from the instant device, which lies substantially under the toe. Claims 7-9 and 15-23 depend from claims 1, 10, and 18, and include the limitation, "not extending under a first metatarsal." Therefore, the '314 patent cannot render claims 7-9 and 15-23 obvious. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 7-9 and 15-17 were rejected as being obvious over the '472 patent in view of either U.S. Patent No. 4,745,927, issued to Brock ("the '927 patent"), or U.S. Patent No. 4,940,046, issued to Jacoby ("the '046 patent"). It appears that the '314 patent is also included in this rejection. To the extent that this rejection applies to the amended claims, it is respectfully traversed.

As previously discussed, neither the '472 patent nor the '314 patent, alone or in combination, discloses or suggests the orthopedic apparatus of amended claims 1 and 10. The '927 patent and the '046 patent fail to compensate for the deficiencies noted in these two prior art references. Accordingly, these claims are patentable over the combination of these references. Claims 7-9 and 15-17, which depend from independent claims 1 and 10, respectively, are similarly patentable for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

#### **Conclusion**

Claims 1-23 have been shown to be allowable over the prior art. Applicants believe this reply to be fully responsive to all outstanding issues and place this application in condition for allowance. If this belief is incorrect, or other issues arise, do not hesitate to contact the undersigned or his associates at the telephone number listed below. Please apply any charges not covered, or any credits, to Deposit Account 50-0591 (Reference Number 09166.002001).

Respectfully submitted,

Date: \_\_\_\_\_

*7/6/03*



Jonathan P. Osha, Reg. No. 33,986  
ROSENTHAL & OSHA L.L.P.  
1221 McKinney Street, Suite 2800  
Houston, TX 77010

Telephone: (713) 228-8600  
Facsimile: (713) 228-8778